



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): **Harry R. Davis et al.**

Application No.: **10/057,629**

Filed: **January 25, 2002**

For: **Use of Substituted Azetidinone  
Compounds for the Treatment  
Of Sitosterolemia**

Group Art Unit: 1617

Examiner: San Ming R. Hui

Case No.: **CV01382K US**

Date: **April 8, 2005**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

(a) Pursuant to the duty of disclosure under 37 C.F.R. § 1.56, it is requested that the documents listed on the accompanying Form PTO-1449 be considered and made of record in the above-identified patent application. Copy(ies) of these documents ☒ are enclosed ☐ were filed in related U.S. Application No(s) \_\_\_\_\_ filed \_\_\_\_\_, respectively.

(b) No fee is believed to be due because:

- ☐ This Information Disclosure Statement is being submitted concurrently with the filing of the above-identified application; **or**
- ☐ This Information Disclosure Statement is being submitted within three (3) months of the filing date of the above-identified application; **or**
- ☐ This Information Disclosure Statement is being submitted concurrently with a Request for Continued Examination (RCE); **or**
- ☐ This Information Disclosure Statement is being submitted prior to the mailing of a first Office Action on the merits.

(c) ☐ This Information Disclosure Statement is being submitted before the mailing date of any final action, notice of allowance, or an action that otherwise closes prosecution; and:

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; **or**
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in

§ 1.56(c), more than three months prior to the filing of this Information Disclosure Statement; **or**

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

(d) ☒ This Information Disclosure Statement is being submitted on or before the payment of the issue fee; and:

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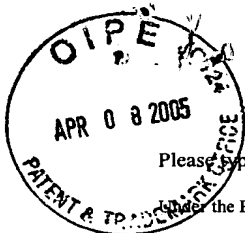
☒ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. **23-0650**.

Respectfully submitted,

Dated: **April 8, 2005**  
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/057,629
				Filing Date	January 25, 2002
				First Named Inventor	Harry R. Davis et al.
				Group Art Unit	1617
				Examiner Name	San Ming R. Hui
Attorney Docket Number	CV01382KUS/4686-045584				
Sheet	1	of	1		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cite and/or country where published.	T <sup>2</sup>	
	1	Nguyen LB, et al., "A molecular defect in hepatic cholesterol biosynthesis in sitosterolemia with xanthomatosis" J Clin Invest, 86: 923-931 (1990)		
	2	Lien B. Nguyen, et al., "Regulation of Cholesterol biosynthesis in sitosterolemia: effects of lovastatin, cholestyramine, and dietary sterol restriction" Journal of Lipid Research, Vol. 32, pp. 1941-1948 (1991)		
	3	T.A. Miettinen, "Inhibition of cholesterol absorption by HMG-CoA reductase inhibitor" Eur J Clin Pharmacol (1991) 40 [Suppl 1]: S19-S 21		
	4	H. Vanhanen, et al., "Pravastatin Lowers Serum Cholesterol, Cholesterol-Precursor Sterols, Fecal Steroids, and Cholesterol Absorption in Man", Metabolism, Vol. 47, No. 6 (June), (1992) pp. 588-595		
	5	Matti I.J. Uusitupa, et al., "Lathosterol and Other Noncholesterol Sterols During Treatment of Hypercholesterolemia With Lovastatin Alone and With Cholestyramine or Guar Gum" Arteriosclerosis and Thrombosis, Vol. 12, No. 7, 807-813 (1992)		
	6	Zetia Product Brochure, Merck/Schering-Plough Pharmaceuticals (October 2002).		
	7	R. Steiner et al., "Sitosterolemia", <a href="http://www.emedicine.com/ped/topic_2110.htm">http://www.emedicine.com/ped/topic_2110.htm</a> (4/5/2005).		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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